

**Rational Pharmaceutical Management Plus  
Introduction of Antiretroviral Therapy in Mombasa, Kenya:  
Trip Report of Technical Assistance to Support Program  
Implementation  
January 27 to February 10, 2004**

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## **About RPM Plus**

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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## Contents

Acronyms .....	v
Background .....	2
Purpose of Trip .....	3
Scope of Work .....	3
Activities .....	6
1. Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested. Discuss issues for supporting scaling up of ART initiatives. ....	6
2. Work with Port Reitz District Hospital pharmacy staff to develop SOPs for the pharmacy in preparation for start up of the ART Program. Address other pharmacy-related issues as agreed in the implementation plan developed in December 2003. ....	6
3. In collaboration with FHI/IMPACT work with Bomu Medical Centre to develop the clinical services, pharmacy and laboratory implementation plans in preparation for the start up of the ART Program. ....	6
4. Capacitate CPGH pharmacy staff in quantifying requirements of ARVs. ....	7
5. Attend the first Mombasa ART Program Operations Committee meeting. ....	7
6. Work with FHI/IMPACT, Horizons and site staff to develop a unified MIS system for the ART Program; review draft indicators, methodology, instruments and mechanisms for feedback. ....	7
7. Assist in strengthening the pharmacy and laboratory MIS at CPGH to support inventory management and service delivery.....	7
8. Meet with other key stakeholders, and local partners within the Kenyan Government, MOH, other cooperating agencies and partners to inform implementation of the Mombasa ART Program, as appropriate. ....	7
<i>Briefing of Provincial Medical Officer on January 29, 2004</i> .....	8
<i>CPGH Eligibility Committee/CPGH Implementation Team Meeting on January 29, 2004</i> ..	8
<i>Meeting with Magongo Municipal Clinic staff on February 3, 2004</i> .....	8
<i>Meeting with Horizons on February 5, 2004</i> .....	8
Collaborators and Partners.....	8
USAID .....	8
FHI .....	9
Population Council/Horizons .....	9
Site staff.....	9
Adjustments to Planned Activities and/or Additional Activities .....	9
Next Steps .....	10
Annex 1. USAID Briefing Note, February 3, 2004: <i>Mombasa ART Program -Update on RPM Plus MIS Activities.</i> ....	12
Annex 2. <i>Introduction of Antiretroviral Therapy in Mombasa, Kenya: Update on Pharmacy and Laboratory Implementation Progress and Report of Visit to Provide Technical Assistance January 28 to February 4, 2004</i> .....	14



## **Acronyms**

ADR	adverse drug reaction
AHFS	American Hospital Formulary Service
AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral [drugs]
CCC	Comprehensive Care Centre [CPGH]
CDC	U.S. Centers for Disease Control and Prevention
CPGH	Coast Provincial General Hospital
CPK	creatine phosphokinase
DAART	Directly Administered Antiretroviral Therapy
DUR	drug utilization review
FHI	Family Health International
ELISA	enzyme-linked immunosorbent assay
GOK	Government of Kenya
HDL	high-density lipoprotein
HIV	human immunodeficiency virus
ICRH	International Centre for Reproductive Health
IMPACT	Implementing AIDS Prevention and Care Project [FHI]
KEMRI	Kenya Medical Research Institute
LDL	low-density lipoprotein
M&E	monitoring and evaluation
MIS	management information system
MOH	Ministry of Health [Kenya]
MSH	Management Sciences for Health
NASCOP	National AIDS and Sexually Transmitted Diseases Control Programme [Kenya]
OHA	[USAID] Office of HIV/AIDS
OPD	out patient department [CPGH]
PBMC	peripheral blood mononuclear cells
PEP	post exposure prophylaxis [for HIV]
PMO	Provincial Medical Officer [Coast Province]
QA	quality assurance
QC	quality control
RDU	rational drug use
RPM	Rational Pharmaceutical Management Plus [Program]
SO4	[USAID/Washington] fourth strategic objective
SOP	standard operating procedure
TAP	technical assistance partners [IMPACT/RPM Plus/Horizons]
USAID	U.S. Agency for International Development
U.S.HHS	U.S. Department of Health and Human Services
VCT	voluntary counseling and testing [HIV]
WHO	World Health Organisation





## **Background**

Management Sciences for Health (MSH)/Rational Pharmaceutical Management Plus (RPM Plus) Program has received funding from the United States Agency for International Development (USAID) under USAID's fourth strategic objective (SO4) to collaborate with Family Health International (FHI)/Implementing AIDS Prevention and Care Project (IMPACT) and Population Council/Horizons to support the Government of Kenya (GOK) and local partners to introduce antiretroviral therapy (ART) into the existing health care system of four facilities in the Mombasa District of Kenya's Coast Province, as part of a package of comprehensive prevention, care and treatment. The Mombasa ART Program will provide valuable implementation and operations research on how to safely and effectively deliver antiretrovirals (ARVs) and how to build capacity to expand access to treatment. The dissemination of assessment and implementation results, tools, and lessons learned is an important component of this activity.

In September 2001, RPM Plus accompanied representatives from USAID/Office of HIV/AIDS (OHA) and USAID/Kenya to meetings with the Minister of Health, the Permanent Secretary for Health, the Minister of Public Health, the Director of Medical Services and the Chairman of the Pharmacy and Poisons Board of Kenya to discuss the Mombasa ART Program, drug registration, procurement and other drug management issues. RPM Plus also accompanied representatives from OHA, Kenya Mission, FHI/IMPACT, and Horizons on a site visit to Mombasa where the team met with the Provincial Medical Officer (PMO) for Mombasa, the Chief Administrator and Chief Pathologist at Coast Provincial General Hospital (CPGH), and local partners.

In April 2002, RPM Plus along with FHI/IMPACT and Horizons participated in a workshop in Mombasa with local partners, stakeholders and GOK Ministry of Health (MOH) to finalize the proposal and to draw up a timeline for the assessment.

In September 2002, RPM Plus conducted an assessment of the capacity of the pharmaceutical management system and laboratory services to support the introduction of ART in 4 sites in Mombasa, in addition to assessing current access to and use of ARVs in Mombasa city.

In November 2002, RPM Plus presented the results of a pharmaceutical management system and laboratory services assessment conducted from September 5 to 29, 2002 at a meeting of stakeholders. Invited participants included members of the Steering Committee and also other key stakeholders and partners, including representatives from the four sites.

In January 2003, RPM Plus met with the implementation team and key partners at each of the four sites to present and solicit feedback on the results of the pharmaceutical management system and laboratory services assessment. In addition, RPM Plus in collaboration with FHI/IMPACT worked with the implementation team at CPGH to select and prioritize options and recommendations to develop an implementation plan in preparation for the start up of the Mombasa ART Program.

Capacity building activities at CPGH began in January 2003 and an initial multidisciplinary training was held at the end of March 2003. CPGH was the first of the four proposed implementing sites to begin delivering ART – ARVs were dispensed to the first patient on



June 3, 2003. RPM Plus has been providing ongoing technical assistance to CPGH to support implementation of strategies to strengthen the pharmaceutical management system and laboratory services to support the start up and scale up the ART Program in addition to working with the other sites to prepare for the introduction of ART.

In October 2003, RPM Plus in collaboration with FHI/IMPACT worked with the implementation team at Port Reitz District Hospital to select and prioritize options and recommendations to develop implementation plans in preparation for roll out of the ART Program to this second site.

In November 2003, RPM Plus conducted a review of the Mombasa ART Program six months after the introduction of ART at CPGH in collaboration with FHI/IMPACT and Horizons. RPM Plus focused on the technical issues for the pharmaceutical management system and laboratory services, FHI/IMPACT on clinical services and overall implementation, and Horizons on operations research.

### **Purpose of Trip**

Ms. Helena Walkowiak traveled to Kenya from January 27 to February 10, 2004 to assist in preparing two new sites in Mombasa, Port Reitz District Hospital and Bomu Medical Centre, for start up of the ART program. In addition, Ms. Walkowiak provided site-specific support for the implementation of the ART Program at CPGH. Mr. Hare Ram Bhattarai traveled to Kenya from January 27 to February 6, 2004 to work with FHI/IMPACT to continue work on developing the management information system (MIS) for the Mombasa ART program and to continue developing and testing monitoring and evaluation (M&E) indicators and instruments at the sites.

### **Scope of Work**

Scope of work for Ms. Helena Walkowiak (January 27 to February 10, 2004)

1. Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested. Discuss issues for supporting scaling up of ART initiatives.
2. Work with Port Reitz District Hospital pharmacy staff to develop the standard operating procedures (SOPs) for the pharmacy in preparation for start up of the ART Program. Address other pharmacy-related issues as agreed in the implementation plan developed in December 2003.
3. In collaboration with FHI/IMPACT, work with Bomu Medical Centre to develop the clinical services, pharmacy and laboratory implementation plans in preparation for the start up of the ART Program.
4. Capacitate CPGH pharmacy staff in quantifying requirements of ARVs.
5. Attend the first Mombasa ART Program Operations Committee meeting.
6. Work with Mr. Bhattarai, the RPM Plus Management Information System (MIS) specialist, FHI/IMPACT and Horizons to develop the unified MIS system.
7. Meet with other key stakeholders, and local partners within the Kenyan Government, MOH, other cooperating agencies and partners to inform implementation of the Mombasa ART Program, as appropriate.

Scope of work for Mr. Hare Ram Bhattarai (January 27 to February 6, 2004)

1. Participate in an arrival briefing and a departure debriefing for USAID/Kenya, if requested.
2. Work with FHI/IMPACT, Horizons and site staff to develop a unified MIS system for the ART Program; review draft indicators, methodology, instruments and mechanisms for feedback.
3. Assist in strengthening the pharmacy and laboratory MIS at CPGH to support inventory management and service delivery
4. Meet with other key stakeholders, and local partners within the Kenyan Government, MOH, other cooperating agencies and partners to inform implementation of the Mombasa ART Program, as appropriate.



## **Activities**

### **1. Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested. Discuss issues for supporting scaling up of ART initiatives.**

On February 4, 2004 Ms. Walkowiak, Mr. Bhattarai, Dr Michael Thuo, the Regional Technical Advisor for RPM Plus and Mrs Jedida Wachira, RPM Plus Senior Program Associate met and debriefed Mr. Buck Buckingham and Dr. John Wasonga at USAID/Kenya on RPM Plus activities during the visit. Mr. Bhattarai presented an update on RPM Plus MIS activities for the Mombasa ART program to date together with the draft RPM Plus M&E plan and instruments. This summary is included as Annex 1.

Mr. Buckingham informed the RPM Plus representatives that Dr. Wasonga has been appointed by USAID/Kenya as Project Management Specialist HIV/AIDS and will be assisting Mr. Buckingham in coordinating care and support activities. Ms. Cheryl Sönnichsen will be coordinating prevention activities. Mr. Buckingham has been appointed as the Interagency Coordinator for the President's Emergency Plan on HIV/AIDS Relief (the Emergency Plan) for Kenya. Mr. Buckingham and Dr. Wasonga informed the RPM Plus representatives that USAID and the U.S. centers for Disease Control (CDC) would hold a partners meeting in the near future to discuss next steps for the Emergency Plan.

### **2. Work with Port Reitz District Hospital pharmacy staff to develop SOPs for the pharmacy in preparation for start up of the ART Program. Address other pharmacy-related issues as agreed in the implementation plan developed in December 2003.**

On January 30, 2004 Ms. Walkowiak and Mrs Wachira met with the pharmacy staff from Port Reitz District Hospital to develop the Pharmacy SOPs for the ART Program. The next steps are for RPM Plus to prepare the first draft of the SOPs for review by the pharmacy staff at Port Reitz District Hospital. RPM Plus also reviewed other essential activities that need to be addressed in the pharmacy before the ART program can begin. The approval of the implementation plan and discussions on infrastructure issues are pending the arrival of the new Medical Officer of Health for Port Reitz District Hospital.

### **3. In collaboration with FHI/IMPACT work with Bomu Medical Centre to develop the clinical services, pharmacy and laboratory implementation plans in preparation for the start up of the ART Program.**

Ms. Walkowiak and Mrs Wachira met with the ART Implementation Team at Bomu Medical Centre to develop the implementation plans for pharmacy and laboratory in preparation for start up of the ART program. Dr. Adungosi from FHI/IMPACT was unable to attend the meeting so the development of the clinical services implementation plan was delayed. The next steps are to draft the implementation plans for review and approval by the management team at Bomu Medical Centre. On February 3, 2004 RPM plus met with the pharmaceutical technologist in charge of the pharmacy and the purchasing officer at Bomu Medical Centre to develop the Pharmacy SOPs for the ART Program. The next steps are for RPM Plus to prepare the first draft of the SOPs for review by the pharmacy and management staff at Bomu Medical Centre.

**4. Capacitate CPGH pharmacy staff in quantifying requirements of ARVs.**

This activity was deferred due to the absence of the pharmacist in charge of the ART program at CPGH who was on leave during this trip. During this visit RPM Plus assisted CPGH Pharmacy to quantify requirements for the fourth order to be placed using USAID funding since the start up of the program.

**5. Attend the first Mombasa ART Program Operations Committee meeting.**

The first meeting of the Operations Committee was postponed.

**6. Work with FHI/IMPACT, Horizons and site staff to develop a unified MIS system for the ART Program; review draft indicators, methodology, instruments and mechanisms for feedback.**

Mr. Bhattarai, Ms. Walkowiak and Mrs Wachira met with FHI representatives Dr. Adungosi, Dimitri Prybylski, and Edward Wandia to discuss the concept of a unified MIS system. FHI/IMPACT expressed their interest in working to develop a common system. The partners shared draft indicators and instruments. Next steps are for FHI to work closely with NASCOP on developing a national MIS for ART programs. FHI will keep the technical partners informed of developments at the national level.

**7. Assist in strengthening the pharmacy and laboratory MIS at CPGH to support inventory management and service delivery**

The draft indicators for monitoring the implementation of the ART Program in the pharmacy and laboratory were shared with CPGH staff for review and comment. A format that monitors ART-related pharmacy activities on a bimonthly basis was put on test at CPGH pharmacy. A format that monitors ART-related laboratory activities was put on test at CPGH laboratory. A meeting was held with the internal audit committee to hand over a tool that facilitates auditing of pharmacy-related activities for testing. The next steps are for RPM Plus to follow up with the CPGH departments and committees on the results of the tests in April 2004 and to revise and finalise the tools accordingly.

A client satisfaction survey format was drafted for pharmacy and laboratory for inclusion in the Horizons client satisfaction survey. Finally a tool to track expiry dates of ARVs was reported to be very useful for this purpose by CPGH Pharmacy. RPM Plus will now produce plastic coated versions.

An update on MIS activities is attached as Annex 1.

**8. Meet with other key stakeholders, and local partners within the Kenyan Government, MOH, other cooperating agencies and partners to inform implementation of the Mombasa ART Program, as appropriate.**

***Briefing of Provincial Medical Officer on January 29, 2004***

Representatives of the technical assistance partners met with the Dr. Kahindi, to update him on the Mombasa ART Program with a particular focus on MIS. Dr. Kahindi informed the partners that it was planned that the district management information system be reviewed at the end of March. He also emphasized the importance of developing sustainable MIS systems.

***CPGH Eligibility Committee/CPGH Implementation Team Meeting on January 29, 2004***

Ms. Walkowiak and Mrs Wachira attended the weekly meeting to review eligibility of new patients for the program. A meeting of the CPGH Implementation team followed where the pharmacist in charge of the ART Program at CPGH led discussions on operationalising the ART ADR monitoring and reporting system. The roles and responsibilities of individual staff, forms and procedures for monitoring and reporting adverse drug reactions to antiretroviral drugs at CPGH were reviewed and discussed. Next steps are for RPM Plus to revise the SOP based on discussions and for CPGH to test the revised form and system. The form and SOP will be revised and finalized based on the test in April 2004.

***Meeting with Magongo Municipal Clinic staff on February 3, 2004***

Ms. Walkowiak, Mr. Bhattarai and Mrs Wachira met with the Sister-in-Charge, the pharmacy and laboratory staff to discuss the scheduled repeat of the initial training proposed for February 2004 and to identify the staff that would attend.

During this visit, the Sister-in-Charge notified RPM Plus that the availability of essential drugs at Magongo Clinic had deteriorated severely and that no drug orders had been received by the clinic for seven months.

***Meeting with Horizons on February 5, 2004***

Ms. Walkowiak, Mrs Wachira, Mr. Hare Ram Bhattarai and Dr. Thuo met with Mr. Rick Hoffman in Nairobi to discuss data collection for the costing component of the Mombasa ART Program. Next steps are for RPM Plus to identify the variables to be followed over the course of the program and to keep an ongoing program narrative.

A full report of progress to date on the Mombasa ART Program is provided in Annex 2: *Introduction of Antiretroviral Therapy in Mombasa, Kenya: Update on Pharmacy and Laboratory Implementation Progress and Report of Visit to Provide Technical Assistance January 28 to February 4, 2004*. This report was prepared for the PMO and for staff at the four implementing sites.

**Collaborators and Partners**

***USAID***

Buck Buckingham, USAID/Kenya  
John Wasonga, USAID/Kenya

***FHI***

John Adungosi, FHI/Mombasa  
Dimitri Prybylski, FHI Washington  
Edward Wandia, FHI/Nairobi

***Population Council/Horizons***

Rick Hoffman, FHI/Washington

***Site staff***

CPGH Management and Implementation Team  
Port Reitz District Hospital Management and Implementation Team  
Bomu Medical Centre Management and Implementation Team  
Magongo Municipal Clinic Implementation Team

**Adjustments to Planned Activities and/or Additional Activities**

The activity to capacitate CPGH pharmacy staff in quantifying requirements of ARVs was deferred due to the absence of the pharmacist in charge of the ART program at CPGH who was on leave during this trip.

The first meeting of the Operations Committee was postponed.

## **Next Steps**

1. RPM Plus will work in collaboration with USAID/OHA, USAID/Kenya, partner cooperating agencies, the local government and local partners, to provide technical assistance to strengthen the pharmaceutical management system and the laboratory services at CPGH, Port Reitz District Hospital and Bomu Medical Centre to support the introduction of ART as agreed in the implementation plans. The next steps for this are set out in Annex 2.

RPM Plus will draft the Port Reitz District Hospital Pharmacy SOPs for review by pharmacy staff in January 2004.

RPM Plus will draft the Bomu Medical Centre Pharmacy SOPs for review by pharmacy staff in January 2004.

RPM Plus will support CPGH to finalise and approve SOPs developed for the ART Program

- RPM Plus will work with pharmacy and administrative staff to review the testing of the CPGH SOP for the internal audit in April 2004.
  - The SOP for ADR monitoring and reporting system will be tested by CPGH and revised by RPM Plus in April, 2004.
2. RPM Plus will continue to work closely with FHI to develop a unified MIS system for the Mombasa ART program. The MIS tools and instruments that are put on test at CPGH pharmacy and laboratory will be revised based on the test results in April 2004.
  3. The report of the six monthly review conducted in November 2003 will be finalized and disseminated to MOH, USAID, ART Program sites, stakeholders and technical assistance partners in April 2004. The technical assistance partners will work with CPGH site staff and stakeholders to review and update the implementation plans as necessary based on the findings identified in May 2004.
  4. The final report of the RPM Plus assessment will be finalized and disseminated by end of April, 2004.





## **Annex 1. USAID Briefing Note, February 3, 2004: *Mombasa ART Program - Update on RPM Plus MIS Activities.***

Prepared by Hare Ram Bhattarai, RPM Plus

### Visit in October 2003

- Attended meeting with other partners where all partners agreed to create a single database that provides information for clinical, pharmacy and laboratory activities. This system was perceived as 'unified MIS'. Each partner decided to work independently to list information requirements in their area of intervention
- Visited all four sites (CPGH, Port Reitz District Hospital, Bomu Medical Centre and Magongo Municipal Clinic) to get a sense of the ground realities and studied the current system of data collection

### Out of Country work

- Worked with other RPM Plus staff and consultants to list the indicators for monitoring the service volume, commodity movement and quality aspects of pharmacy and laboratory related activities.
- Developed M&E plan for the pharmacy and laboratory related activities.
- A simple tool to monitor the expiry dates of ARV drugs was created and put on test at CPGH pharmacy

### Visit in Jan-Feb 2004

- Attended meeting with FHI and discussed further about 'unified MIS' concept. FHI continued their interest to work towards the creating a common system.
- As the indicators for Pharmacy and Laboratory were ready they are shared with CPGH pharmacy and laboratory staff for their comment and suggestions.
- A format that monitors ART related pharmacy activities on a bimonthly basis is now put on test at CPGH pharmacy. This format monitors the movement of drugs supplied by both USAID and GOK
- A format that monitors ART related laboratory activities is also put on test at the CPGH laboratory
- A client satisfaction survey format (for pharmacy and laboratory activities) is drafted that will be sent to Horizons as they are shortly initiating the client satisfaction survey.

- The use of tool to track the expiry dates of ARVs was reported to be very useful by CPGH Pharmacy. RPM Plus will now produce some plastic coated versions so that they can be reused.
- A meeting with internal audit committee at CPGH was organized and handed over a tool that facilitates auditing of pharmacy related activities for testing.

#### Current Status

- Indicators for monitoring pharmacy and laboratory activities are at the finalization stage
- Some of the tools that collect data on a routine basis are put on test
- All partners are in good communication in the development of MIS.
- After the tools are tested and indicators are finalized, computerization of the system is expected to follow
- Same tools with no or little modification can then be used at other sites once the program is implemented.

***Annex 2. Introduction of Antiretroviral Therapy in Mombasa, Kenya: Update on  
Pharmacy and Laboratory Implementation Progress and Report of  
Visit to Provide Technical Assistance January 28 to February 4, 2004***

**Summary of Activities to Provide Technical Assistance  
January 28 to February 4, 2004**

- Drafting of Standard Operating Procedures for the Pharmacy at Port Reitz District Hospital in preparation for start up of the ART Program
- Development of Implementation Plans for Pharmacy and Laboratory at Bomu Medical Centre in preparation for start up of the ART Program
- Drafting of Standard Operating Procedures for the Pharmacy at Bomu Medical Centre in preparation for start up of the ART Program
- Assist the CPGH ART Implementation Team to review the roles and responsibilities, forms and procedures for monitoring and reporting adverse drug reactions to antiretroviral drugs at CPGH.
- Review draft MIS indicators and instruments with CPGH Pharmacy and Laboratory; hand over instruments for testing
- Prepare for repeat of initial ART training schedules for February/March 2004.

## **Coast Provincial General Hospital**

### **Update on Pharmacy Implementation Progress – February 4, 2004**

Progress to date and next steps are reported for each of the key areas outlined in the CPGH Implementation Plan – developed January 2003.

#### **A. Policies and Standards**

##### **1. Guidelines**

###### **Progress to date:**

The following guidelines are now available in the Pharmacy

- Kenya ARV Therapy Guidelines: 2002 Edition
- Kenya Guidelines For Prevention & Management of Opportunistic Infections and Tumours in HIV/AIDS: 2002 Edition
- Scaling up Antiretroviral Therapy in Resource-limited Settings WHO 2002
- WHO Formulary 2003
- U.S. HHS Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents
- U.S. HHS Guidelines for the Use of Antiretroviral Agents in Paediatric HIV Infection

###### **Next steps:**

To assist CPGH Pharmacy to replace guidelines when updated copies are issued.

##### **2. Standard Operating Procedures (SOPs) for the ART Program**

###### **Progress to date and Next Steps:**

<b>Standard Operating Procedure</b>		<b>Status – February 4, 2004</b>
	Roles and Responsibilities of the CPGH Pharmacy Department in Support of the ART program <ul style="list-style-type: none"><li>○ Pharmacist in charge of the ART Program</li><li>○ Pharmacist in charge of the ARV bulk store</li><li>○ Pharmacy staff member in charge of dispensing ARVs from the outpatient pharmacy</li><li>○ Pharmacy staff member in charge of preparing prepacks for DAART study</li><li>○ Pharmacist in charge of checking prepacking for DAART study</li></ul>	<p>All these SOPs have been reviewed by CPGH Pharmacy.</p> <p>All these SOPs were presented to the Scientific Committee on December 4, 2003 for review. The Scientific Committee approval/suggested changes were still pending as of February 4, 2004. If approved the SOPs will then be presented to the CPGH Management Committee.</p>

Standard Operating Procedure		Status – February 4, 2004
102	Receipt of Antiretroviral Drugs at ARV Bulk Store	<p>All these SOPs have been reviewed by CPGH Pharmacy.</p> <p>All these SOPs were presented to the Scientific Committee on December 4, 2003 for review. The Scientific Committee approval/suggested changes were still pending as of February 4, 2004. If approved the SOPs will then be presented to the CPGH Management Committee.</p>
103	Record Keeping at ARV Bulk Store	
104	Internal Antiretroviral Drug Distribution	
105	External Antiretroviral Drug Distribution	
106	Record Keeping at the Outpatient Pharmacy	
107	Issuing Antiretroviral Drugs to Outpatients	
108	Issuing Antiretroviral Drugs to Inpatients	
201	Shipment Discrepancy Report	
202	Stock Count Discrepancy Report	
302	Medication Error Reporting	
401	Temperature Control	
403	Security of Antiretroviral Drugs	
	CPGH ART Drug Management Flow Charts <ul style="list-style-type: none"> <li>○ Requesting and Receipt of Antiretroviral Drugs</li> <li>○ Issuing Antiretroviral Drugs from the ARV Bulk Store</li> <li>○ Dispensing Antiretroviral Drugs from the Outpatient Pharmacy</li> </ul>	
109	Medication Use Counselling on Antiretroviral Therapy	<p>Has been reviewed by CPGH Pharmacy and information has been harmonised with ICRH and FHI materials. Drug interactions have been added</p> <p>This SOP was presented to the Scientific Committee on December 4, 2003 for review. The Scientific Committee approval/suggested changes were still pending as of February 4, 2004. If approved the SOP will then be presented to the CPGH Management Committee.</p>

Standard Operating Procedure		Status – February 4, 2004
110	Prepacking Antiretroviral Drugs for the DAART Study	SOP has been reviewed and form had an initial test. Final test will be done when DAART study is up and running. This SOP was presented to the Scientific Committee on December 4, 2003 for review. The Scientific Committee approval/suggested changes were still pending as of February 4, 2004. If approved the SOPs will then be presented to the CPGH Management Committee.
501	Internal Audit of Antiretroviral Drugs	Is being revised to simplify the form  Next step – the SOP and form will be tested by the Quality Committee.  SOP and form will be revised and presented to the Scientific Committee for approval in May 2004
502	ART Program: Pharmacy Activity Report	Is being revised to simplify the form  Next step – the SOP and report will be tested by the Pharmacy  SOP and report will be revised and presented to the Scientific Committee for approval in May 2004
301	Antiretroviral Therapy Adverse Drug Reaction Monitoring and Reporting.	SOP was revised in January 2004 to incorporate policy decisions made by Scientific Committee on December 4, 2003. The SOP was reviewed by CPGH ART Implementation Team on January 29, 2004. SOP and form will be revised to incorporate the suggested changes and handed to CPGH for testing.  SOP and report will be revised based on testing and presented to the Scientific Committee for approval in May 2004

### 3. Other Standard Operating Procedures for the Pharmacy

**Progress to date:** None

**Next steps:**

RPM Plus will work with CPGH Pharmacy to start drafting other non-ART Program related SOPs in April 2004.

## **B. Infrastructure/Equipment**

### **Progress to date:**

- Lockable cupboards installed in ARV bulk store
- Sliding doors installed to be used as lockable cupboards for DAART prepacks
- Air conditioner installed in ARV bulk store
- Refrigerator purchased for ARV bulk store
- Cupboards grilled for security in outpatient pharmacy
- Booths installed for patient medication use counselling
- Thermometers purchased and temperature monitoring in place for ARV bulk store and refrigerator
- Handed over to CPGH – CPGH providing ongoing maintenance
- Thermometer for outpatient pharmacy was purchased and temperature monitoring set up – temperatures are constantly exceeding the recommended temperature of 25°C. Average temperature in November 29°C.

### **Next steps**

- CPGH to follow up on repairs/poor workmanship
  - Install more secure locks on cupboard in ARV bulk store
  - Stabilise cupboard in ARV bulk store
  - Sliding doors are jammed – plane down doors
  - Adjust locks on the grills of four cupboards in outpatient pharmacy - do not line up and they cannot be locked.
- RPM Plus will discuss options with CPGH to cool the outpatient pharmacy

## **C. Human Resources - Training**

### **Progress to date:**

- 2 pharmacists & 2 pharmaceutical technologists trained in April 2003 – 5 day training
- 1 pharmacist is being trained in the NASCOP training, December 1-5, 2003.
- Topics have been identified by CPGH staff for ongoing training
- Training modules have been developed for Adverse Drug Reaction Monitoring and reporting and Counselling.

### **Next steps:**

- The 5 day initial training will be repeated in February 2004 for new staff or staff that missed the initial training in April 2003
- Ongoing training will begin April 2004. CPGH will provide the venue and organise the logistics.

## **D. Human Resources - Staffing**

### **Progress to date:**



- Roles and responsibilities of pharmacy staff for the ART program have been drafted and approved by CPGH Pharmacy staff
- Key responsibilities (e.g. issuing from ARV bulk store and receiving into the outpatient pharmacy) have been separated
- Weekly pharmacy rota identifying staff members to perform key responsibilities has been initiated

**Next steps:**

- Stabilising staffing levels and increasing participation of a larger number of staff in ARV bulk store management, dispensing and counselling for ART patients and prepacking is key to the success of scaling up the ART Program
- Counselling ART patients can take 30 minutes for first visit and 10-15 minutes for ongoing visits – has implications for staffing as ART Program scales up.
- Organise a catch up workshop for staff that missed initial ART training in February 2004.

## **E. Stores/Supply Management**

**Progress to date:**

- Record keeping for ARVs as per GOK MOH standard procedures are in place
- RPM Plus is providing technical assistance to CPGH for quantifying requirements
- 4 requests for procurement of ARVs have been submitted to FHI by CPGH
- FHI, RPM Plus and CPGH Pharmacy staff held a second meeting on December 1, 2003 to discuss procurement issues with a particular focus on streamlining the process for ordering supplies, returning stock supplied in error, assuring acceptable shelf life and exchanging short dated stock.

**Next steps:**

- Develop a quantification methodology
- Train and hand over quantification to CPGH staff – by August 2004

## **F. Use of ART**

### **1. Prescribing and dispensing**

**Progress to date:**

- Dr Olwande is a member of the Eligibility Committee and acts as Secretary. As a member is quickly able to update Eligibility List and to prepare for new patients
- The following books have been supplied to CPGH Pharmacy
  - AHFS Drug Information (2003)
  - Drugs in Pregnancy and Lactation
  - Martindale: The Complete Drug Reference (2002)
  - British National Formulary (March 2003)
- Pharmacy is now preparing for dispensing for paediatric patients – labels will be printed by ICRH and meetings have been held with Paediatric AIDS Clinic to discuss dispensing issues

**Next steps:**

- Pharmacy to produce a weekly list of availability of all drugs for CCC to assist prescribing
- Problems with availability of sequentially numbered prescriptions need to be addressed

### **2. Medication Use Counselling**

**Progress to date:**

- Four staff members have been trained and are available to counsel patients on ART medication – rota provides details of availability and contact information

- SOP has been developed and CPGH/RPM Plus has worked with ICRH/Horizons and FHI to harmonise all information being given out on side effects
- A drug interaction component has been added into the Counselling SOP
- Training materials on Medication Use Counselling for Pharmacy Staff have been drafted

**Next steps:**

- Pharmacy staff are often being asked about non-medication issues. FHI to prepare standard information for frequently asked questions to assist pharmacy staff
- Pharmacy to work with FHI on developing patient information leaflets on ART
- Produce poster at Window 4 on ART Counselling
- Pharmacy to work on identifying strategies to improve patient flow at Pharmacy booths for non-ART patients to reduce crowding at the hatches.

### **3. ADR monitoring and reporting system**

**Progress to date:**

- SOP and monitoring and reporting forms have been drafted and revised based on initial input from CPGH pharmacy and medical staff
- Meetings of the Scientific Committee have been postponed to date.
- Training materials on ADR monitoring and reporting have been drafted
- The SOP was presented to Scientific Committee for policy decisions on December 4, 2003.
- SOP and forms were revised based on Scientific Committee decisions in January 2004 and presented to the CPGH ART Implementation Team for review and planning for operationalising the SOP.

**Next steps:**

- The form and SOP will be tested by CPGH in March 2004. Final revisions to the SOP and form will be made at this time.
- Revise and finalise training materials based on policy decisions and deliver ADR training
- Submission to Scientific Committee for approval may be delayed until later in 2004 to allow adequate time for testing.

### **4. RDU monitoring and reporting**

**Progress to date:** None

**Next steps:**

- One pharmacist from CPGH will attend the WHO/MSH regional workshop on Promoting the Rational Use of Drugs in February 2004.
- The pharmacist will develop a plan for promoting RDU and begin basic Drug Utilisation Reviews (DUR) in April 2004.

### **5. Dispensing for DAART study**

**Progress to date:**

- SOP and form has been developed and tested
- Responsibilities for preparing prepacks and checking have been split

**Next steps:**

- As DAART study has only just started and there are few patients to test the system – the SOP and forms need to be retested once the prepacking system is running at full scale
- DAART cupboard in CCC needs to be secured with a bar – ICRH following up
- As many of the ARVs are thermo labile, all DAART storage cupboards should have temperature monitoring – ICRH to follow up

## **G. Management Information System**

### **Progress to date:**

- Manual systems for inventory management and patient profiles have been set up and are up and running smoothly at current work level
- RPM Plus and FHI had a meeting and site visits in October 2003 to identify strategies to improve efficiency in data collection and data quality and reporting for ART Program.
- In January 2004, RPM Plus shared the draft indicators and instruments with CPGH Pharmacy for testing
- RPM Plus is assisting four pharmacy staff to attend basic computer training in preparation for computerisation of inventory management system.

### **Next steps:**

- The MIS instruments will be revised in April 2004 based on testing of the instruments
- RPM Plus will continue to work with FHI to develop a plan for a unified MIS system for the ART program

## **H. Monitoring and Evaluation/Performance Improvement**

### **Progress to date:**

- SOP and forms for internal audit (internal to CPGH but external to the pharmacy) is being simplified.
- ART Program Activity Report provides information for performance monitoring and also acts as a management tool – provides information on workload and administrative issues that are impacting the ART Program. The SOP and report was tested by the CPGH Pharmacy in September 2003 and is now being simplified.
- In November 2003, the TAP partners worked with CPGH to review progress and performance at six months of the Mombasa ART Program. RPM Plus worked collaboratively with CPGH to identify the areas of interest to be covered in the review and to identify stakeholders to be interviewed. The pharmacy staff and CPGH management were debriefed on the findings.

### **Next steps:**

- Complete and disseminate the results of the six monthly review to all stakeholders.
- In April 2004, RPM Plus will hold a meeting with CPGH and stakeholders to review and revise the implementation plans for pharmacy and laboratory based on the results of the six monthly review.

- CPGH to appoint 2 members of the Quality Committee and 1 administrative person to Internal Audit Committee
- Internal Audit Committee to test SOP and forms. SOP and form will be revised and presented to the Scientific Committee for approval in May 2004.
- ART Program Activity Report - SOP and form will be revised and presented to the Scientific Committee for approval in May 2004.

## **Coast Provincial General Hospital**

### **Update on Laboratory Implementation Progress – February 4, 2004**

Progress to date and next steps are reported for each of the key areas outlined in the CPGH Laboratory Implementation Plan which was finalised in August 2003.

#### **A. Policies and Procedures**

##### **1. Guidelines**

###### **Progress to date:**

The following guidelines are now available in the Laboratory

- Kenya ARV Therapy Guidelines: 2002 Edition
- Kenya Guidelines For Prevention & Management of Opportunistic Infections and Tumours in HIV/AIDS : 2002 Edition
- Kenya VCT Guidelines: Latest edition

###### **Next steps:**

- To assist CPGH Laboratory to replace guidelines when updated copies are issued.

##### **2. Standard Operating Procedures (SOPs) for the ART Program**

###### **Progress to date:**

- SOPs have been developed and tested for:
  - Processing Chemistry Specimens
  - Criteria for rejecting chemistry specimens
  - Correcting erroneous reports
  - Alanine aminotransferase analysis by Photometer 5010
  - Aspartate aminotransferase analysis by Photometer 5010
  - $\gamma$ -Glutamyl Transferase analysis by Photometer 5010
  - Alkaline phosphatase analysis by Photometer 5010
  - Direct bilirubin analysis by Photometer 5010
  - Amylase analysis by Photometer 5010
  - Total bilirubin analysis by Photometer 5010
  - Total protein analysis by Photometer 5010
  - Blood urea analysis by Photometer 5010
  - Creatinine analysis by Photometer 5010
  - Chiron diagnostic 644 Na/K Analyser
  - Complete blood cell count by Coulter Analyser
  - Manual white cell differential count and platelet estimate
  - Sample preparation for CD4 T cell determination by Cytoflow
  - Specimen collection, storage and delivery for viral load testing
  - Sample collection
  - Cell separation: PBMC
  - Post exposure prophylaxis
  - Laboratory Critical/Panic Values
  - Thermometer quality control
  - Refrigerator/freezer maintenance

- The SOPs were presented to the Scientific Committee on December 4, 2003 for review.

**Next steps:**

- The Scientific Committee approval/suggested changes are still pending as of February 2004. When approved the SOPs will then be presented to the CPGH Management Committee.
- SOPs to be prepared and tested for
  - Performing CD4 tests
  - Performing cholesterol, triglycerides, LDL, HDL when these tests become available
  - Performing serum lactate and CPK tests when these tests become available at CPGH
  - Record keeping in the laboratory
  - Procurement, storage, inventory management of reagents used in laboratory procedures at CPGH;
- SOPs to be presented to the Scientific Committee for approval in May 2004
- Other laboratory SOPs (not specifically related to ART Program) – development to begin May 2004

## **B. Infrastructure/Equipment**

**Progress to date:**

- CD4 CyFlow (including an initial supply of reagents and tubes) arrived in October 2003. 4 members of staff have been trained to perform CD4 testing. 108 tests have been performed to date in CPGH laboratory.
- FHI has placed orders for
  - Multichannel pipettes
  - Precision Pipettes
  - Rotors
- RPM Plus has assisted CPGH to provide basic computer training for the 4 staff operating the CD4 CyFlow – lack of computer experience is adding 10 minutes to the testing time for each test,

**Next steps**

- The TAP partners to discuss with CPGH on how to secure the machine.
- CPGH had planned to repair the Autolab which would substantially decrease the workload currently involved in using the backup system. However, it has been found that the Autolab is not repairable. The next step is to identify options on how to proceed.
- Monitor need for other equipment/upgrades as program scales up

## **Human Resources – Training**

### **Progress to date:**

- 4 lab technologists trained in April 2003 – 5 day training
- Topics have been identified by CPGH staff for ongoing training
- List of key books/reference materials have been identified

### **Next steps:**

- The 5 day initial training will be repeated in February 2004 for new staff or staff that missed the initial training in April 2003
- Ongoing training will begin April 2004. CPGH will provide the venue and organise the logistics.

## **C. Human Resources – Staffing**

### **Progress to date:**

- Roles and responsibilities of ART Program Laboratory Coordinator have been developed by CPGH. Dr Denje, laboratory supervisor has been identified to take on the duties initially

### **Next steps:**

- Review additional workload 3 monthly and develop plan for long term

## **D. Blood Specimen Collection**

### **Progress to date:**

- Register has been set up in the outpatient department (OPD) to record all patients bled and samples collected
- Regular collection service has been established to bring samples from OPD to the main lab and return results to CCC
- Lab request forms and reporting forms have been drafted and are being tested by CCC
- Registers have been established in each section of lab

### **Next steps:**

- Improve labelling of samples

## **E. Testing**

### **1. HIV Diagnosis**

#### **Next steps:**

- Shortages of HIV rapid kits and ELISA reagents are impacting the program and need to be followed up on

### **2. Haematology and Clinical Chemistry**



**Progress to date:**

- RPM Plus began providing assistance to strengthen inventory management information system in January 2004 to address shortages of haematology and clinical reagents which are impacting the program

**Next steps:**

- RPM Plus will assist CPGH to quantify needs for calibration reagents in budget
- CPGH to procure reagents for calibration and to institutionalise calibration

**CD4**

**Progress to date:**

- CD4 CyFlow (including an initial supply of reagents and tubes) arrived in October 2003. 4 members of staff have been trained to perform CD4 testing. 108 tests have been performed to date in CPGH laboratory.
- RPM Plus is assisting CPGH to identify and institute to provide external quality control for the CD4 CyFlow. A survey of facilities will be conducted in February 2004.
- RPM Plus is assisting CPGH to provide basic computer training for the 4 staff operating the CD4 CyFlow – lack of computer experience is adding 10 minutes to the testing time for each test,

**Next steps**

- The TAP partners to discuss with CPGH on how to secure the machine.

**3. Viral Load**

**Progress to date:**

- Baseline samples are not being collected and stored for possible future testing due to the lack of -80 freezer storage space
- Survey to identify appropriate facility has been performed. KEMRI has been identified for an initial 3 month contract – to continue based on performance
- FHI/RPM Plus have visited KEMRI to discuss contract and preparation of samples for testing.

**Next steps:**

- CPGH/FHI to identify -80 freezer storage for samples
- FHI to set up viral load testing at KEMRI
- RPM Plus to develop SOP for preparing and transporting samples for viral load testing

**4. Viral Resistance Testing**

**Progress to date:**

- Baseline samples are not being collected and stored for possible future testing due to the lack of -80 freezer storage space

**Next steps:**

- CPGH/FHI to identify -80 freezer storage for samples
- RPM Plus to follow up to monitor process

**F. MIS**

**Progress to date:**

- Lab request and reporting forms have been drafted and are currently being tested
- In January 2004, RPM Plus shared the draft indicators and instruments with CPGH Laboratory for testing
- RPM Plus is assisting four pharmacy staff to attend basic computer training in preparation for computerisation of inventory management system.

**Next steps:**

- The MIS instruments will be revised in April 2004 based on testing of the instruments
- RPM Plus will continue to work with FHI to develop a plan for a unified MIS system for the ART program

**G. Good Laboratory Practice**

**Progress to date:**

- An accident/incident register has been set up
- SOP for PEP has been developed

**Next steps:**

- Develop training materials to promote Good Laboratory Practice in CPGH Laboratory.

**H. Monitoring and Evaluation/Quality Control**

**Progress to date:**

- In November 2003, the TAP partners worked with CPGH to review progress and performance at six months of the Mombasa ART Program. RPM Plus worked collaboratively with CPGH to identify the areas of interest to be covered in the review and to identify stakeholders to be interviewed. The Chief Pathologist and CPGH management were debriefed on the findings.
- The laboratory technologists were debriefed in April 2004 on findings of six monthly review.

**Next steps:**

- RPM Plus to complete and disseminate the results of the six monthly review.
- In April 2004, RPM Plus will hold a meeting with CPGH and stakeholders to review and revise the implementation plans for pharmacy and laboratory based on the results of the six monthly review.

- Develop a plan to strengthen QA/QC in lab

## **I. Financing**

### **Next steps:**

- Need to develop a policy for non-ART Program patients seeking CD4 testing at CPGH
- Need to determine whether patients being retested for HIV as screening for the ART program will be charged a fee

## **Implementation at Port Reitz District Hospital, Bomu Medical Centre and Magongo Municipal Clinic**

### **Update on Pharmacy and Laboratory Implementation Progress**

#### **A. Port Reitz District Hospital (PRDH)**

##### **Progress to date**

- Site assessment was conducted in September 2002, results presented to site for feedback in January 2003.
- 1 pharmaceutical technologist and 1 lab technologist were trained in April 2003 – 5 day training
- FHI and RPM Plus met with PRDH staff in October 2003 to draft implementation plans for introduction of ART for service delivery, pharmacy and laboratory.
- Port Reitz District Hospital staff commenced partnering assignments with CPGH in December 2003. Medical staff are working with Dr Otieno, nursing staff with CCC staff, pharmacy staff with Dr Olwande and laboratory staff with Mr Denje.
- In January 2004, RPM Plus met with PRDH staff to develop draft Pharmacy SOPs for the ART Program. Work began on collecting information to draft the SOPs for PRDH laboratory.

##### **Next steps**

- Implementation is pending approval of the plan by PRDH Management.
- FHI will hold a meeting with the 4 sites in March 2004 to discuss issues around collaboration for the ART program e.g. transfer of specimens for laboratory testing, different cost sharing policies
- A repeat of the 5 day initial training is planned for February 2004 – for new staff or staff that missed the initial training
- Ongoing training will begin April 2004.

#### **B. Bomu Medical Centre**

##### **Progress to date**

- Site assessment was conducted in September 2002, results presented to site for feedback in January 2003.
- 1 pharmaceutical technologist and 1 lab technologist were trained in April 2003 – 5 day training
- Two follow on visits to the laboratory were made in July/August 2003.
  - No new equipment has yet been purchased and donors are still to be identified. (Bomu Medical Centre are requesting donations of a colorimeter and Autolab)
- Bomu Medical Centre staff commenced partnering assignments with CPGH in December 2003. Medical staff are working with Dr Otieno, nursing staff with CCC staff, pharmacy staff with Dr Olwande and laboratory staff with Mr Denje.

- RPM Plus met with Bomu Medical Centre staff on January 30, 2004 to draft implementation plans for introduction of ART for pharmacy and laboratory.
- In February 2004, RPM Plus met with Bomu Medical Staff staff to develop draft Pharmacy SOPs for the ART Program. Work began on collecting information to draft the SOPs for Bomu Medical Centre laboratory.

### **Next steps**

- Implementation is pending approval of the plan by Bomu Medical Centre Management.
- FHI will hold a meeting with the 4 sites to discuss issues around collaboration for the ART program in March 2004 e.g. transfer of specimens for laboratory testing, different cost sharing policies
- FHI will meet with Bomu Medical Centre staff in February 2004 to develop implementation plan for clinical services for the introduction of ART
- A repeat of the 5 day initial training is planned for February 2004 – for new staff or staff that missed the initial training
- Ongoing training will begin April 2004.

## **C. Magongo Municipal Clinic**

### **Progress to date**

- Site assessment was conducted in September 2002, results presented to site for feedback in January 2003.
- 1 pharmaceutical technologist and 1 lab technologist were trained in April 2003 – 5 day training – however, since then , the trained staff at Magongo have been transferred
- Municipal Council – health officer have all been replaced. FHI and RPM Plus met with the Medical Officer for Health (Dr Chidagaya) and Deputy (Dr Were) to brief them on the ART Program.
- New Sister at Magongo has been briefed on the ART program and provided with a copy of al assessment results
- Two follow on visits to the laboratory were made in July/August 2003.
- RPM Plus visited the clinic on February 3, 2004 to discuss the logistics around repeating the initial training in later in February 2004.

### **Next steps**

- FHI will hold a meeting with the 4 sites to discuss issues around collaboration for the ART program e.g. transfer of specimens for laboratory testing, different cost sharing policies in March 2004.
- A repeat of the 5 day initial training is planned for February 2004 – for new staff
- Ongoing training will begin April 2004.

### **List of activities January 28 to February 4, 2004**

#### **January 29 Thursday**

Dr Kahindi, Provincial Medical Officer – courtesy visit; objectives of visit  
Meet with FHI to discuss unified MIS  
CPGH Eligibility Committee meeting and meeting to discuss operationalising the ADR monitoring and reporting system for ART

#### **January 30 Friday**

Dr Shikely – courtesy visit; objectives of visit  
Meeting with Port Reitz District Hospital pharmacy staff to develop SOPs  
Meeting with Bomu Medical Centre team to develop implementation plans for pharmacy and laboratory to support start up of ART Program

#### **January 31 Saturday**

Meeting with Dr Olwande, pharmacy CPGH on MIS

#### **February 2, Monday**

Meeting with Dr Mandaliya and Mr Denje at CPGH Laboratory on MIS forms and indicators  
Collection of data at CPGH for quantification of needs for procurement

#### **February 3 Tuesday**

Meeting with CPGH Quality Committee to hand over internal audit tool for testing by CPGH Audit Committee  
Meeting with Magongo sister, pharmacy and laboratory staff on training  
Meeting with Bomu Medical Centre pharmacy and purchasing officer to develop first draft of Pharmacy SOPs for ART Program

#### **February 4 Wednesday**

Debriefing at USAID/Kenya